K040802

APR 2 8 2004

510(k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	William G. McLain Manager, Regulatory Affairs Phone: 610-378-0131, ext. 3323 Fax: 610-478-3188 Email: bill.mclain@arrowintl.com
Date summary prepared:	March 26, 2004
Device trade name:	Probe Jacket for the HemoSonic™ 200 Hemodynamic Monitor.
Device common name:	Sheath, Jacket or Sheath Jacket.
Device classification name:	FED; 21 CFR Part 876.1500; Sheath, for Endoscope
Legally marketed devices to which the device is substantially equivalent:	The predicate device is the jacket used in Arrow International, the HemoSonic™ 200 Hemodynamic Monitor cleared under K031153.
Description of the device:	The probe jacket contains the acoustic gel into which the ultrasound crystals are placed. It consists of a plug rod, tip cap, hub, body, acoustic gel and tip.
Intended use of the device:	The probe jacket is an accessory to the HemoSonic™ 200 Hemodynamic Monitor.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate device(s).
Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: • tensile strength, • acoustic properties, • simulated insertion, and • biocompatibility.
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2004

Arrow International, Inc.
c/o Mr. William G. McLain
Manager, Regulatory Affairs
2400 Bernville Road
Reading, PA 19605

Re: K040802
HemoSonic™ 200 Hemodynamic Monitor
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPN
Dated: March 26, 2004
Received: March 29, 2004

Dear Mr. McLain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochmel

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040802

Device Name: HemoSonic™ 200 Hemodynamic Monitor

Indications For Use:

The HemoSonic™ 200 can be used to observe, diagnose, evaluate, and monitor at-risk patients from 15 to 150 kg by providing hemodynamic information for determining therapeutic actions and maintaining cardiovascular stability.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of Cardiovascular Devices

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